

REMARKS

Applicants wish to express their appreciation to the Examiner for withdrawing the finality of the previous Office Action.

Claims 11-17, 20, and 21 are objected to because of their dependency upon rejected claims. Claims 1, 2, 5-10, 18, and 19 are rejected under 35 U.S.C. 103 (a) as being unpatentable over *Bryans et al.* (US 7,141,606) (referred to herein as "Bryans") in view of *Berge et al.* (J. of Pharmaceutical Sciences, 66, no. 1, Jan. 1977, p. 1-19) (referred to herein as "Berge").

In the prior Office Action, all pending claims 1, 2, and 5-21 were rejected as being obvious over Bryans in view of Berge. Apparently, Applicant's arguments convinced the Examiner as to the nonobviousness of claims 11-17, 20, and 21 because these claims are merely objected to in the present Office Action. In an effort to better place the application in condition for appeal, Applicants have added new claims 22-28 herein, which rewrite several of the objected to claims in independent form. In particular, new claim 22 is old claim 11 in independent form; new claim 23 is old claim 12 in independent form; new claim 24 is old claim 13 in independent form; new claim 25 is old claim 16 in independent form; new claim 26 is old claim 17 but dependent on claim 25; new claim 27 is old claim 20 in independent form; and new claim 28 is dependent on new claim 27. Accordingly, these new claims should be allowed by the Examiner.

Applicants have not amended or cancelled any of the pending claims 1, 2, and 5-21 and the present rejection is again traversed.

Bryans

Bryans discloses a compound, which can be gabapentin, for use in treating sleep disorders. Bryans states that the compound can be prepared in various salt forms (hydrochloric, sulphuric, phosphoric, acetic, oxalic, lactic, citric, malic, salicylic, malonic, maleic, succinic, methanesulfonic acid). The Examiner admits that Bryans does not disclose gabapentin tannate. Nor does Bryans teach or suggest any methods for making gabapentin tannate (or any other gabapentin salts for that matter).

Berge

Berge is a review article published in 1977 discussing various pharmaceutical salts. Berge mentions tannate salts, along with a laundry list of about 70 other possibilities (see Table

I- FDA approved commercially marketed salts (as of 1974)). Berge does not mention gabapentin, or any gabapentin salts.

The Examiner's argument is that one skilled in the art would "be motivated to use the tannate for the salt of gabapentin for sleep disorders; this is because Berge et al expressly teaches that one of the FDA-approved commercially marketed salts can be the tannate." Applicants disagree with this "obvious to try" argument. Bryans already teaches that the gabapentin can be a salt of various organic or inorganic acids (hydrochloric, sulphuric, phosphoric, acetic, oxalic, lactic, citric, malic, salicylic, malonic, maleic, succinic, methanesulfonic acid). There is no suggestion that any other salt would be better than those already listed. Moreover, Berge teaches away from the Examiner's argument that one skilled in the art would try to make a gabapentin salt with tannate, or any other of the 70 possibilities. On page 1, bottom of left column, Berge states "[c]hoosing the appropriate salt, however, can be a very difficult task, since each salt imparts unique properties to the parent compound." And also, on page 1, right column "[u]nfortunately, there is no reliable way of predicting the influence of a particular salt species on the behavior of the parent compound." The Examiner completely ignores these statements in Berge and instead uses his or her own judgment that one of skill in the art would envision a reason for making gabapentin tannate or conclude there is a reasonable expectation of successfully forming gabapentin tannate, based upon Bryans and Berge.

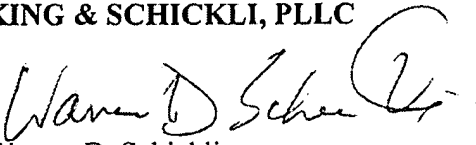
As Applicants previously argued, to establish a prima facie case of obviousness, the Examiner must determine "whether there was an apparent reason to combine" the prior art references to derive the claimed invention. The Examiner argues that the reason to combine Bryans and Berge is because 1) Bryans teaches that gabapentin can be prepared as a salt, and 2) Berge teaches that tannate can be used as a pharmaceutical salt. But the law states that a prima facie case of obviousness must rest on a reason to combine found in the references themselves. In this case that is not true. Bryans nowhere suggests that one should look to salts other than those specifically mentioned and Berge nowhere suggests that tannate has any particular advantages which would lead one to examine its use over the other 66 or so possibilities.

Applicants again respectfully submit that the Examiner has failed to establish a prima facie case of obviousness in the rejection of the claims. Applicants respectfully request reconsideration of the rejection of claims 1, 2, and 5-21 and urge the Examiner to proceed with a Notice of Allowance.

In summary, all the pending claims patentably distinguish over the prior art and should be formerly allowed. Upon careful review and consideration it is believed the examiner will agree with this proposition. Accordingly, the early issuance of a formal Notice of Allowance is earnestly solicited.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read "Warren D. Schickli", with a large, stylized flourish at the end.

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